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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,898	08/22/2003	Joar Opheim	03-109	1343
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FOOTHILL LAW GROUP			GHALI, ISIS A D	
777 N. FIRST STREET, SUITE 325				
SAN JOSE, CA 95112			ART UNIT	PAPER NUMBER
			1611	
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			05/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/646,898	OPHEIM, JOAR
Examiner	Art Unit	
Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 31 January 2008.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-9 and 14-16 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-9, 14-16 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's amendment filed 01/31/2008.

Claims 10-13 have been previously canceled, and claim 16 is currently added.

Claims 1-9, and 14-16 are pending and included in the prosecution.

The following rejection has been overcome by virtue of applicant's amendment and remarks:

The rejection of claims 1-9, and 14-16 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement

The following rejection has been previously discussed, and is maintained for reasons of record:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-9, and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lachman et al. in combination with US 5,955,102 ('102) and US 5,718,323 ('323).

Lachman teaches a capsule shell comprising gelatin, plasticizer, water and flavor. The amount of plasticizer is calculated to be 40-60% and chosen according to the end use of the capsule and the effect of encapsulated material on the shell. The amount of water is calculated to be 70-130% but water is lost during drying process. The flavor is present in a concentration of 0.1% to impart the desirable taste in chewable capsule (page 407, right column).

Lachman does not teach the claimed amount of the water and plasticizer, or fish oil as a dietary supplement.

However, Lachman suggested that plasticizer is chosen according to the end use of the capsule and the effect of encapsulated material on the shell, and this teaching would have motivated one having ordinary skill in the art to adjust the amount of plasticizer according to the intended use and encapsulated material.

Additionally, Lachman teaches that the water is lost during drying process, i.e. the amount is expected to be radically reduced below 70%. Note that applicant discloses in page 6 of the specification, lines 1-2, that the amount of water present in the shell is 10-45%, and that amount is reduced to 8+/-2% after drying of the capsule. The reference does not disclose if the amount before drying or after drying.

In any event, the amount of water and plasticizer do not impart patentability to the claims, absent evidence to the contrary.

Fish oil is well known dietary supplement, and also known to be provided in a gelatin capsules combined with flavoring agents.

US '102 teaches fish oil is preferably provided in a gelatin capsule (abstract; col.2, lines 31-36).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide shell of gelatin capsule as disclosed by Lachman that comprises gelatin, softener, water and small amount of flavor and use the capsule to deliver fish oil disclosed by US '102, motivated by the teaching of US '102 that the gelatin capsules are the preferred delivery method for the fish oil, with reasonable expectation of having a gelatin capsule comprising shell containing 1% of flavoring agent to impart the desired taste as disclosed by Lachman to deliver fish oil to the patient in need of such a nutrient with great success.

The combination of Lachman and US '102 does not explicitly teach water-soluble fruit flavors.

US '323 teaches soft gelatin capsule shell comprising flavoring agent selected from essential oils and fruit flavor or combinations thereof (col.5, lines 43-49). Examples C9 and C10 showed lemon flavor. Fruit flavors are expected to be water-soluble since compounds and their properties are inseparable.

Therefore, the prior art recognized gelatin capsules with flavored shell, and also recognized the equivalency as well as the combination of essential oil flavors and fruit flavors.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide gelatin capsule to deliver fish oil comprising shell containing 1% of flavoring agent including essential oil to impart the desired taste as disclosed by the combined teaching of Lachman and US '102, and further add fruit flavor or replace the essential oil with the fruit flavor, especially lemon flavor, as disclosed by US '323, motivated by the desire of US '323 to flavor the shell of gelatin capsule with essential oil or fruit flavors, or their combination, with lemon flavor exemplified as a preferred flavor, with reasonable expectation of having gelatin capsule to deliver fish oil comprising shell containing 1% of fruit flavor, and specially lemon flavor, to impart palatable taste to unpleasant fish oil content of the capsule to successfully improve patient compliance.

Response to Arguments

3. Applicant's arguments filed 01/31/2008 have been fully considered but they are not persuasive. Applicant argues that Lachman teaches only two flavorings one of them is insoluble and the other not known of soluble or insoluble. US '323 teaches fruit flavors, and does not recognize the importance of using water soluble flavor. None of the references teach narrow ranges recited by the present claims. Applicant therefore concludes that it would not have been obvious to one having ordinary skill in the art to use water soluble flavoring in the range of amounts recited by the claims.

In response to the above argument, it is noticed that applicant argues against the references individually, and one cannot show nonobviousness by attacking references

individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant admits that Lachman teaches one soluble flavoring agent, and this would have suggested to one having ordinary skill in the art at the time of the invention to use soluble flavoring agent, even if the reference teaches other flavoring agents that may not be soluble. Additionally, Lachman teaches the flavor is present in a concentration of 0.1% to impart the desirable taste in chewable capsule, and this falls within the range of the claimed amounts of between 0.1 to 1.5. Lachman further teaches that the amount of flavoring is further reduced during drying of the capsule, and this teaching implies higher concentration of the flavoring agent in the shell of the capsule. US '323 is relied upon for teaching the fruit flavors in the capsule shell, and it teaches lemon flavor that is claimed by applicant and that is water soluble since compounds and their properties are inseparable. Therefore, the water soluble flavor in the capsule is taught by both Lachman and US '323 and further Lachman teaches the same amount as instantly claimed. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references

themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide gelatin capsule to deliver fish oil comprising shell containing 1% of flavoring agent including essential oil to impart the desired taste as disclosed by the combined teaching of Lachman and US '102, and further add fruit flavor or replace the essential oil with the fruit flavor, especially lemon flavor, as disclosed by US '323, motivated by the desire of US '323 to flavor the shell of gelatin capsule with essential oil or fruit flavors, or their combination, with lemon flavor exemplified as a preferred flavor, with reasonable expectation of having gelatin capsule to deliver fish oil comprising shell containing 1% of fruit flavor, and specially lemon flavor, to impart palatable taste to unpleasant fish oil content of the capsule to successfully improve patient compliance.

It has been held that “When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.” *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). “When the question is whether a patent claiming the combination of elements of prior art is obvious,” the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.”

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Applicant argues that the declaration under 37 CFR 1.132 filed 04/10/2006 and the commercial success on 09/25/2006 are sufficient to overcome the nonobviousness rejection of the claims.

In response, it is noticed that the objective evidences are insufficient to overcome the rejection of the claims based upon U.S.C. 103 (a) as set forth in the last Office action because: there was no showing that the objective evidence of nonobviousness as well as commercial success are commensurate in scope with the claims. See MPEP § 716. The scope of the claims is broad covering all flavors in amounts of 0.1% to 1.5%, while the declaration is limited only to one flavor, lemon flavor, at specific concentration of 1.0% in the shell and 1.0% in the content of the capsule, even it mention range from 0.25-1.5%, but no showing of unexpected results of range as low as 0.25% or as high as 1.5%. No showing of effect of range below the lower range of claimed amount or over the upper range of the claimed amount to establish superiority of the results. Furthermore, no showing that the commercially successful product is the same as the claimed product. The species of the flavoring agent in specific concentration in the shell composition and specific amount in the content of the capsule of the declaration does not support the generic concept of the claims encompassing wide ranges and various flavors. There is no comparative data between the claimed amount of the flavor with

amounts outside the upper and the lower ends of the claimed range. Objective evidence of nonobviousness must be commensurate in scope with claims that evidence is offered to support. See in *Greenfield and DuPont* 197 USPQ 227 (CCPA 1978); *In re Boesch and Slaney* 205 USPQ 215 (CCPA 1980); and *In re Tiffin and Erdman* 170 USPQ 88 (CCP 1971). The declaration includes statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See MPEP § 716.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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